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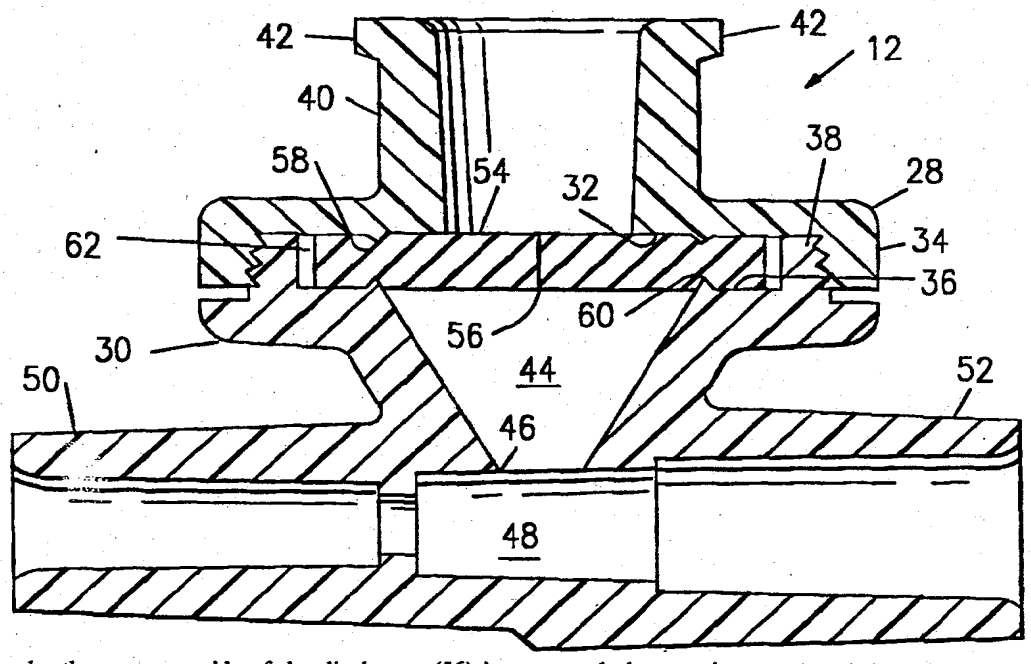
(57) Abstract

A syringe actuated valve (12) for filling an IV solution bag (14) or the like includes an upstream housing portion (28), configured as a female Luer fitting (40) to receive and lock with the male Luer tip and Luer lock fitting (64) of a typical syringe (24), and a downstream portion (30) having an internal passage (48). The upstream portion has a first annular base (32) and the downstream portion has a second annular base (36), the first base (32) being wider in the radial dimension than is the second base (36). A resilient diaphragm (54) having a normally closed central slit (56) has an upstream side seated against the first base (32) and a downstream side seated against the second base (36), whereby the upstream side of the diaphragm (56) is supported closer to its center, and through a greater portion of its radial dimension than is the downstream side of the diaphragm.



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VALVE FOR FILLING IV SOLUTION BAG

Background of the Invention

The present invention relates generally to the field of syringe-actuated valves used in medical applications for filling intravenous solution bags and like containers with a liquid medicament solution. More specifically, the present invention relates to a syringe-actuated valve that permits (a) the filling of such containers with a first liquid medicament by means of a syringe; (b) the withdrawal of air or excess liquid from the container during the filling process by means of the syringe; and (c) the introduction, by means of a syringe, of a second liquid medicament into the infusion line during the intravenous administration of the first medicament from the bag into the patient.

The intravenous administration of drugs to a patient requires that a collapsible container ("IV bag") be filled with a specified volume of the desired drug or medicament in liquid form. Typically, this filling process is performed by having a nurse or other medical practitioner fill a previously empty bag from a supply container. The filled bags can be used immediately or stockpiled for later use.

One method of filling an IV bag comprises the steps of withdrawing a volume of the medicament from the supply container with a syringe, and then injecting the medicament into the bag through an infusion line, by means of a valve that permits the liquid to flow into the bag from the syringe, but which prevents backflow out of the valve when the syringe is removed. In other words, the valve is opened in response to the introduction of the syringe, and closed in response to the withdrawal of the syringe. Thus, the bag may be

filled by serial applications of the syringe without leakage or backflow out of the valve, and the valve may be left in the infusion line after the filling is completed, and the infusion line is introduced into the patient's vein.

The concept of a syringe-actuated valve, wherein the valve is opened by the introduction of a syringe, and closes in response to the withdrawal of the syringe, is well-known in the prior art. A number of such valves have been developed, for example, for the purpose of introducing a secondary, or supplemental, liquid medicament into an intravenous infusion line during the administration of a primary liquid medicament from an IV bag. Representing such prior art valves are the following U.S. patents: 4,439,182 - Huang; 3,994,293 - Ferro; 3,416,567 - Von Dardel et al.; 4,683,916 - Raines; 4,915,687 - Sivert; 4,819,684 - Zaugg et al.; 3,710,942 - Rosenberg; and 4,666,429 - Stone. A variation of this concept is presented in U.S. Patent No. 5,169,393 - Moorehead et al., which discloses a valve that permits the introduction of a secondary medicament into an IV line through a slit diaphragm that opens in response to a differential pressure across the diaphragm, resulting from the pressure of the flow of the secondary medicament.

Because none of the above-discussed prior art devices specifically addresses the application of filling an IV bag or the like, they may fall short of meeting one or more of the criteria that should be advantageously met by a valve used in such an application. For example, since the valve typically would remain in the IV line (or "administration set") during the administration of medicament to the patient,

the valve would need to remain closed in response to back pressures received from the patient's vascular system or from the flow of liquid from the IV bag. At the same time, the valve must permit both the introduction of a liquid into the bag through the IV line, and the withdrawal of gas (air) or liquid from the bag, by means of a syringe. Thus, the valve must be opened only in response to the introduction of the syringe into the valve, and, when open, the valve must allow bi-directional flow. For the sake of simplicity of manufacture and reliability of operation, the valve should have few, if any, moving parts, other than a valving element that is displaced from a closed position to an open position by direct contact with the Luer tip of the syringe. Ease of use would dictate that minimal contact force be required to open the valve, thereby allowing the valve to be opened by a minimal degree of insertion of the Luer tip. Furthermore, the valve would need to provide excellent sealing integrity when closed, so that leakage is substantially prevented when the administration set is used to deliver the contents of the IV bag to the patient.

It would thus be advantageous to provide all of the above-noted advantages and meet all of the above-noted criteria in a syringe-actuated valve that is simple and economical to manufacture, and simple and reliable to use.

Summary of the Invention

Broadly, the present invention is a syringe-actuated valve for filling an IV bag or the like from a syringe having a male Luer tip surrounded by a Luer lock fitting, as is normally found on the end of a

syringe for the attachment of a needle, wherein the valve comprises a housing having an upstream portion and a downstream portion. Captured between the two housing portions is a resilient, deformable diaphragm having a normally-closed slit. The upstream portion of the housing includes a syringe-receiving port formed as a female Luer fitting adapted to receive the male Luer tip of the syringe and to lock with the Luer lock fitting on the syringe. The downstream portion of the housing defines a funnel-shaped internal valve passage extending from the downstream side of the diaphragm, and terminating at an entry orifice into a main flow passage defined between first and second opposed tube connection ports.

In use, a first tube is connected between an empty IV bag and the first tube connection port, and a second tube is connected at one end to the second tube connection port, the opposite end of the second tube typically being connected to an intravenous needle. In filling the bag, the second tube is typically closed with a clamp.

A syringe filled with a liquid medicament and having a male Luer tip, as described above, is inserted into the syringe-receiving port and locked therein by the engagement between the female Luer fitting and the Luer lock fitting. The axial dimension of the syringe-receiving port is such that, when the Luer tip is locked into place, the end of the tip presses against the upstream side of the diaphragm so as to open the slit. When the slit is opened, the syringe is emptied, so that the medicament flows through the slit and the internal valve passage downstream therefrom, entering the main flow passage via the entry orifice. Flow then

proceeds through the first tube connection port and the first tube, and then into the bag.

When the syringe is empty, it is unlocked from the syringe-receiving port and withdrawn therefrom. The slit closes as a result of the resilience of the diaphragm, thereby preventing back flow through the valve. Additional syringes filled with medicament can then be successively inserted into the syringe-receiving port to continue the bag filling process until the bag is filled to the desired level. At selected intervals during the filling process, it may be necessary or desirable to remove air or excess liquid from the bag. This is accomplished by locking an empty syringe into the syringe-receiving port so as to open the slit, as described above. The syringe plunger is then withdrawn to remove the air or liquid from the bag via the first tube, the first tube connection port, the internal valve passage, and the slit.

When the administration set is connected to the patient by inserting the IV needle into the patient, a second or supplemental medicament can be introduced into the main flow passage during infusion by means of a syringe inserted into the syringe-receiving port, in the manner described above. Alternatively, the syringe can be used to withdraw liquid from the main flow passage during infusion.

In either case, the valve remains closed, due to the closure of the slit from the resilience of the diaphragm, as long as it is not pressed on its upstream side by the end of the syringe tip. The diaphragm is seated in the housing so that its upstream side is supported closer to the diaphragm's center, and through

a larger proportion of its radial dimension, than is its downstream side, thereby providing a valve seat on the upstream side of the diaphragm that is closer to the center of the diaphragm than is the valve seat on the downstream side of the diaphragm. This structure allows the diaphragm to flex relatively easily to open its slit when physically urged in the downstream direction (i.e., toward the internal passage) by downstream-directed forces applied against its upstream surface, while restraining the diaphragm from flexing in response to upstream-directed forces applied against its downstream surface. As a result, the valve remains closed in response to back pressures generated by the flow from the IV bag, as well as those resulting from the transmission, via the second tube and the second tube connection port, of the vascular pressure of the patient during infusion, thereby further ensuring against leakage.

As will be better appreciated from the detailed description that follows, the instant invention provides a valve mechanism that permits both the introduction of liquid into an IV bag (or the like) and the withdrawal of gas or liquid from the bag, by means of a syringe, thus allowing bidirectional fluid flow, but only in response to the introduction of a syringe into the valve housing. When a syringe is not locked into the housing so as to displace the diaphragm, the valve remains closed, resisting back flow and back pressures with excellent sealing integrity. The valve is simple and economical to construct and use, employing only a single moving part, namely, the diaphragm. The economy and simplicity of construction allow the valve to be manufactured as a disposable

item, yet one that is highly reliable despite its low cost.

Brief Description of the Drawings

Figure 1 is an idealized view of an intravenous administration set incorporating a syringe-actuated IV bag filling valve in accordance with the present invention, showing the use of the valve in filling the bag with a liquid medicament;

Figure 2 is a cross-sectional view of a syringe-actuated IV bag filling valve in accordance with a preferred embodiment of the present invention, showing the valve in its closed position; and

Figure 3 is a cross-sectional view, similar to that of Figure 2, showing the valve being opened by the engagement of a syringe Luer tip against the diaphragm valving element in the valve.

Detailed Description of a Preferred Embodiment

Referring now to the drawings, Figure 1 shows an intravenous (IV) administration set 10 incorporating an IV bag filling valve 12 in accordance with the present invention. The set includes an IV bag 14 fluidly connected by a first tube 16 to the valve 12, and an IV needle 18 fluidly connected by a second tube 20 to the valve 12. The administration set 10 is shown in Figure in use during the filling of the bag 14 with a liquid medicament solution 22 by means of a syringe 24 that is coupled to the valve 12 in the manner to be described below. During this filling process, the second tube 20 is closed by a clamp 26, of conventional design.

An IV bag filling valve 12, in accordance with a preferred embodiment of the invention, is shown in cross section in Figures 2 and 3, Figure 2 showing the valve in its closed state, and Figure 3 in the open

state.

The valve 12 includes an upper or upstream housing portion 28 and a lower or downstream housing portion 30, both of which may be formed of a molded biocompatible polymeric plastic, such as polycarbonate, for example. As shown, the upstream housing portion 28 includes a first annular base 32 from which extends a downwardly-depending peripheral flange 34 that is internally threaded. The downstream housing portion 30 includes a second annular base 36 from which extends an upwardly-extending peripheral rim 38 that is externally threaded to mate with the flange 34 with a sealing fit. The seal between the rim 38 and the flange 34 may be strengthened by an adhesive (not shown), or by ultrasonic welding. Alternatively, to simplify the manufacturing process, the threads on the flange 34 and the rim 38 may be omitted, and the sealing attachment of the two housing portions 28, 30 may be achieved by an adhesive or (preferably) ultrasonic welding alone. When joined together, the two housing portions 28, 30 form a structure resembling a "T"-fitting.

Extending upwardly (as shown in the drawings) from the first annular base 32 of the upstream housing portion is a tubular syringe-receiving port 40, terminating in an open end having a pair of radially-outwardly extending lips 42. As will be described below, the lips 42 allow the exterior of the syringe-receiving port to function as a female Luer fitting. Extending downwardly (as shown in the drawings) from the second annular base 36 of the downstream housing portion 30 is a truncated conical portion defining a funnel-shaped internal valve passage 44 that is wider at its upper (upstream) end than at its lower

(downstream) end. The downstream end of the valve passage 44 terminates in an entry orifice 46, through which the valve passage 44 communicates with a main flow passage 48. The main flow passage 48, in turn, extends between the interior of a first tube connection port 50 and the interior of a second tube connection port 52. The first tube connection port 50 is configured for removable fluid connection with one end of the first tube 16, while the second tube connection port 52 is configured for removable fluid connection with one end of the second tube 20.

A resilient, deformable diaphragm 54, having a normally-closed central slit 56, is provided as the valving element. The slit 56 is preferably a simple linear slit, but alternative configurations, such as a "Y"-shaped slit or an "X"-shaped slit, may be workable. The diaphragm 54, which may be made of a biocompatible elastomeric material, such as silicone or latex, is captured between the upstream housing portion 28 and the downstream housing portion 30 so as to be allowed to flex only in the downstream direction, that is, in response to downstream-directed forces applied against its upstream surface. Specifically, a peripheral portion of the upstream side of the diaphragm 54 is seated against the first annular base 32 on the upstream housing portion 28, while a peripheral portion of the downstream side of the diaphragm is seated against the second annular base 36 on the downstream housing portion 30. Retention of the diaphragm 54, especially against lateral slippage, is enhanced by first and second opposed annular beads 58, 60 on the first and second annular bases 32, 36, respectively.

The first annular base 32 is wider in the radial

dimension than is the second annular base 36. As a result, the upstream side of the diaphragm 54 is supported closer to the diaphragm's center, and through a greater proportion of its radial dimension, than is its downstream side, thereby providing a valve seat on the upstream side of the diaphragm that is closer to the diaphragm's center than is the valve seat on the downstream side.

This structure allows the diaphragm 54 to flex relatively easily to open its slit 56 when physically urged in the downstream direction (i.e., toward the internal valve passage 44) by downstream-directed forces applied against its upstream surface, while restraining the diaphragm from flexing in response to upstream-directed forces applied against its downstream surface.

As mentioned above, the slit 56 is normally closed. The normal closure of the slit 56 is almost purely the result of the physical characteristics (i.e., material and configuration) of the diaphragm 54, and is not significantly the result of biasing by other structure in the valve assembly. In other words, the diaphragm is essentially internally self-biased closed, rather than externally biased.

To assure that any external bias imparted by the adjacent structure is minimized, the outside diameter of the diaphragm is made less than the inside diameter of the downstream housing portion 30 across the peripheral rim 38 that concentrically surrounds the peripheral edge of the diaphragm. Thus, there is an annular space 62 separating the diaphragm 54 from the rim 38, leaving the edge of the diaphragm free of contact with any adjacent structure. The diaphragm 54

is thus physically unconstrained except by the first and second annular bases 32, 36.

The lack of significant external diaphragm bias contributes to the diaphragm's ease of flexing in the downstream direction, while providing enhanced sealing integrity when subjected to upstream-directed forces applied to its downstream surface.

Figure 3 illustrates the opening of the diaphragm's slit 56 by means of the syringe 24. The syringe 24 has a male Luer tip 64 concentrically surrounded by a Luer lock fitting 66 of conventional design. The Luer lock fitting 66 includes an internal thread 68 that engages the lips 42 on the exterior of the syringe-receiving port 40 when the syringe tip 64 is inserted into the interior of the syringe-receiving port, thereby locking the syringe 24 into the syringe receiving port 40. Thus, as previously mentioned, the exterior of the syringe-receiving port 40, with its radially-outwardly extending lips 42, provides a female Luer fitting that locks, in the conventional manner, with the Luer lock fitting 66 on the syringe.

The syringe tip 64 has an outside diameter that is advantageously just slightly less than the inside diameter of the syringe-receiving port 40, so that there is only a small clearance between the tip 64 and the interior surface of the syringe-receiving port 40 when the tip is inserted therein. The relative axial lengths of the tip 64 and the syringe-receiving port 40 are such that when the tip 64 is fully inserted into the syringe-receiving port 40, the distal end of the tip extends slightly past the first annular base 32, thereby engaging the upstream surface of the diaphragm 54 around the slit 56. This engagement presses the

diaphragm in the downstream direction (i.e., into the internal valve passage 44), thereby opening the slit 56, as shown in Figure 3. Since the diaphragm is not externally biased, as discussed above, the degree of opening of the slit 56 is a function only of the physical characteristics of the diaphragm 54 itself, and of the extent of penetration of the syringe tip 64 past the first annular base 32. By proper selection of the material and dimensions of the diaphragm 54, and the length of the slit 56, a relatively large amount of valve opening can be achieved with only a small distance of syringe tip penetration. Indeed, it is readily within the ordinary skill in the pertinent arts (and, therefore, within the scope of the present invention) to fabricate the diaphragm 54 so as to render the slit 56 openable in response to fluid pressure applied to its upstream surface from the syringe, even if the distal end of the syringe tip 64 does not physically contact the diaphragm.

When the requisite degree of force ceases to be applied to the diaphragm's upstream surface (either by the physical contact of the syringe tip or by fluid pressure), the natural resilience of the diaphragm 54 restores it to its normal configuration or position, in which the slit 56 is closed (Figure 2).

In using the present invention to fill the bag 14, the administration set 10 is configured as shown in Figure 1. The first tube 16 is connected between the bag 14 and the first tube connection port 50, and the second tube 20, closed by the clamp 26, is connected at one end to the second tube connection port 52, and at the opposite end to the IV needle 18.

The syringe 24, filled with a liquid medicament

and having the Luer lock fitting 66 around its tip 64, as described above, is inserted into the syringe-receiving port 40 and locked therein by the engagement between the female Luer fitting and the Luer lock fitting 66. When the slit 56 is opened by the force of the syringe tip 64 against the upstream surface of the diaphragm 54, as described above, the syringe is emptied, so that the medicament flows through the open slit and the internal valve passage 44 downstream therefrom, entering the main flow passage 48 via the entry orifice 46. Flow then proceeds through the first tube connection port 50 and the first tube 16, and then into the bag 14.

When the syringe is empty, it is unlocked from the syringe-receiving port 40 and withdrawn therefrom. The slit 56 closes as a result of the resilience of the diaphragm, thereby preventing back flow out of the valve 12 through the syringe-receiving port. Additional syringes filled with medicament can then be successively inserted into the syringe-receiving port to continue the bag filling process until the bag is filled to the desired level.

At selected intervals during the filling process, it may be necessary or desirable to remove air or excess liquid from the bag 14. This is accomplished by locking an empty syringe 24 into the syringe-receiving port 40 so as to open the slit 56, as described above. The syringe plunger is then withdrawn to remove the air or liquid from the bag 14 via the first tube 16, the first tube connection port 50, the internal valve passage 44, and the slit 56.

When the administration set 10 is in use for the infusion of a patient (not shown) by inserting the IV

needle 18 into the patient, a second or supplemental medicament can be introduced into patient through the main flow passage 48, the second tube connection port 52, the second tube 20, and the needle 18 during infusion by means of a syringe 24 inserted into the syringe-receiving port 40, in the manner described above. Alternatively, a syringe 24 can be used to withdraw liquid from the main flow passage 48 during infusion.

In either case, the valve 12 remains closed, due to the closure of the slit 56 from the resilience of the diaphragm 54, as long as no actuating force is applied to its upstream side, either by the physical contact of the distal end of the syringe tip 64, or by the pressure of the fluid exiting therefrom. Moreover, due to the above-described manner in which the diaphragm 24 is seated between the upstream housing portion 28 and the downstream housing portion 30, the slit 56, although easily opened by downstream-directed forces applied to the upstream surface of the diaphragm, strongly resists opening in response to upstream-directed forces applied to the downstream diaphragm surface. As a result, the valve 12 remains closed in response to back pressures generated by the flow from the IV bag 14, as well as those resulting from the transmission, via the second tube 20 and the second tube connection port 52, of the vascular pressure of the patient during infusion, thereby further ensuring against leakage.

It will be appreciated that, in withdrawing air or liquid from the bag 14 during the bag filling procedure, or in withdrawing liquid from the main flow passage 48 during infusion, the syringe tip 64 must

extend past the first annular base 32 so as to open the slit 56 by physically pressing against the diaphragm 54. In other words, the valve cannot be opened simply reducing the fluid pressure on the upstream surface of the diaphragm to less than the pressure on its downstream surface, since, as previously discussed, the seating structure of the diaphragm is such as to resist strongly any significant slit opening in response to such a reverse or back pressure.

Although a preferred embodiment of the instant invention has been shown and described herein, it will be appreciated that a number of variations and modifications, may suggest themselves to those skilled in the pertinent arts. Some of these variations and modifications are mentioned above. Additionally, for example, it may be desirable to configure the upstream and downstream housing portions so that, when joined together, they form a "Y"-fitting. Furthermore, the specific configurations of the internal valve passage 44, the first tube connection port 50, and the second tube connection port 52 should be considered exemplary only. Moreover, the syringe-receiving port 40 may be modified to receive and engage with fittings other than those of the Luer type. These modifications and variations, and others that may suggest themselves to those skilled in the pertinent arts, should be considered within the spirit and scope of the present invention, as defined in the claims that follow.

WHAT IS CLAIMED IS:

1. A syringe-actuated valve for filling a container from a syringe having a male Luer tip surrounded by a Luer lock fitting, wherein the valve comprises:

a housing having an upstream portion and a downstream portion, the upstream housing portion including a syringe-receiving port configured as a female Luer fitting that is lockable with the Luer lock fitting when the male Luer tip is inserted into the syringe-receiving port;

an internal valve passage in the downstream housing portion;

first seating means in the upstream housing portion;

second seating means in the downstream housing portion; and

a resilient diaphragm having a normally-closed slit therein, the diaphragm having an upstream side seated against the first seating means and a downstream side seated against the second seating means, the diaphragm having an upstream surface exposed to the syringe-receiving port and a downstream surface exposed to the internal valve passage;

whereby the first and second seating means allow the diaphragm slit to open to allow fluid communication between the syringe-receiving port and the internal valve passage only in response to downstream-directed forces applied to the upstream surface of the diaphragm, while maintaining the slit in its normally closed position in response to upstream-directed forces applied to the

downstream surface of the diaphragm.

2. The valve of Claim 1, wherein the syringe-receiving port is axially dimensioned so that the male Luer tip engages the upstream surface of the diaphragm so as to open the slit when the Luer tip is inserted into the syringe-receiving port and locked therein by the engagement between the Luer lock fitting and the female Luer fitting provided by the syringe-receiving port.

3. The valve of Claim 1, wherein the first seating means comprises a first annular base and the second seating means comprises a second annular base, and wherein the first annular base is wider in the radial dimension than is the second annular base, so that the upstream side of the diaphragm is supported closer to the center of the diaphragm, and through a greater proportion of its radial dimension, than is the downstream side of the diaphragm.

4. The valve of Claim 1, wherein the diaphragm has a peripheral edge, and wherein the downstream housing portion includes a peripheral rim concentrically surrounding and spaced from the peripheral edge of the diaphragm.

5. The valve of Claim 2, wherein the first seating means comprises a first annular base and the second seating means comprises a second annular base, and wherein the first annular base is wider in the radial dimension than is the second annular base, so that the upstream side of the diaphragm is supported closer to the center of the diaphragm, and through a greater proportion of its radial dimension, than is the downstream side of the diaphragm.

6. The valve of Claim 5, wherein the diaphragm

has a peripheral edge, and wherein the downstream housing portion includes a peripheral rim around the second annular base and concentrically surrounding and spaced from the peripheral edge of the diaphragm.

7. The valve of Claim 1, wherein the upstream and downstream housing portions are attachable to each other by threaded elements.

8. The valve of Claim 5, wherein each of the first and second annular bases includes an annular bead that engages the diaphragm.

9. The valve of Claim 1, wherein downstream housing portion includes a main flow passage in fluid communication with the internal valve passage and extending between first and second tube connection ports, each of which is configured for the removable fluid connection with a fluid-conducting tube.

10. The valve of Claim 9, wherein the internal valve passage is substantially funnel-shaped and extends from the downstream surface of the diaphragm to the main flow passage through an entry orifice, the internal valve passage being wider adjacent the diaphragm than at the entry orifice.

11. A syringe-actuated valve for filling a container from a syringe having a male Luer tip surrounded by a Luer lock fitting, wherein the valve comprises:

a housing having an upstream portion and a downstream portion, the upstream housing portion including a syringe-receiving port configured as a female Luer fitting that is lockable with the Luer lock fitting when the male Luer tip is inserted into the syringe-receiving port;

an internal valve passage in the downstream

housing portion;

a first annular base in the upstream housing portion and a second annular base in the downstream housing portion, the first annular base being wider in the radial dimension than is the second annular base; and

a resilient diaphragm having a normally-closed central slit therein, the diaphragm having an upstream side seated against the first annular base and a downstream side seated against the second annular base, whereby the upstream side of the diaphragm is supported closer to the center of the diaphragm, and through a greater proportion of its radial dimension, than is the downstream side of the diaphragm, the diaphragm further having an upstream surface exposed to the syringe-receiving port and a downstream surface exposed to the internal valve passage.

12. The valve of Claim 11, wherein the diaphragm is substantially unconstrained except where it seats against the first and second annular bases.

13. The valve of Claim 12, wherein the diaphragm has a peripheral edge, and wherein the downstream housing portion includes a peripheral rim concentrically surrounding and spaced from the peripheral edge of the diaphragm.

14. The valve of Claim 11, wherein the syringe-receiving port is axially dimensioned so that the male Luer tip engages the upstream surface of the diaphragm so as to open the slit when the Luer tip is inserted into the syringe-receiving port and locked therein by the engagement between the Luer lock fitting and the female Luer fitting provided by the syringe-receiving

port.

15. The valve of Claim 11, wherein each of the first and second annular bases includes an annular bead that engages the diaphragm.

16. The valve of Claim 11, wherein downstream housing portion includes a main flow passage in fluid communication with the internal valve passage and extending between first and second tube connection ports, each of which is configured for the removable fluid connection of a fluid-conducting tube.

17. The valve of Claim 16, wherein the internal valve passage is substantially funnel-shaped and extends from the downstream surface of the diaphragm to the main flow passage through an entry orifice, the internal valve passage being wider adjacent the diaphragm than at the entry orifice.

18. A syringe-actuated valve for filling a container from a syringe having a male Luer tip surrounded by a Luer lock fitting, wherein the valve comprises:

a housing having an upstream portion and a downstream portion, the upstream housing portion including a syringe-receiving port configured as a female Luer fitting that is lockable with the Luer lock fitting when the male Luer tip is inserted into the syringe-receiving port;

means for attaching the upstream and downstream housing portions to each other;

an internal valve passage in the downstream housing portion;

a first annular base in the upstream housing portion and a second annular base in the downstream housing portion, the first annular base

being wider in the radial dimension than is the second annular base;

a resilient diaphragm having a normally-closed central slit therein, the diaphragm having an upstream side seated against the first annular base and a downstream side seated against the second annular base, whereby the upstream side of the diaphragm is supported closer to the center of the diaphragm, and through a greater proportion of its radial dimension, than is the downstream side of the diaphragm, the diaphragm further having an upstream surface exposed to the syringe-receiving port and a downstream surface exposed to the internal valve passage, the diaphragm being substantially physically unconstrained except where it seats against the first and second annular bases so as to be substantially self-biased in the closed position; and

a main flow passage in the downstream housing portion in fluid communication with the internal valve passage and extending between first and second tube connection ports, each of which is configured for the removable fluid connection of a fluid conducting tube.

19. The valve of Claim 18, wherein the diaphragm has a peripheral edge, and wherein the downstream housing portion includes a peripheral rim concentrically surrounding and spaced from the peripheral edge of the diaphragm.

20. The valve of Claim 18, wherein the syringe-receiving port is axially dimensioned so that the male Luer tip engages the upstream surface of the diaphragm so as to open the slit when the Luer tip is inserted

into the syringe-receiving port and locked therein by the engagement between the Luer lock fitting and the female Luer fitting provided by the syringe-receiving port.

21. The valve of Claim 18, wherein each of the first and second annular bases includes an annular bead that engages the diaphragm.

22. The valve of Claim 18, wherein the internal valve passage is substantially funnel-shaped and extends from the downstream surface of the diaphragm to the main flow passage through an entry orifice, the internal valve passage being wider adjacent the diaphragm than at the entry orifice.

AMENDED CLAIMS

[received by the International Bureau on 07 December 1994 (07.12.94); original claims 2,14 and 20 cancelled; original claims 1,3,4-7,9-11,13,15-19 amended; remaining claims unchanged (7 pages)]

1. (AMENDED) A syringe-actuated valve for filling a container from a syringe having a tapered, hollow, tubular male tip concentrically surrounded by an internally-threaded locking fitting, wherein the valve comprises:

a housing having a proximal portion and a distal portion, the proximal housing portion including a syringe-receiving port configured as an externally-threaded female fitting that is lockable with the locking fitting when the male tip is inserted into the syringe-receiving port;

an internal valve passage in the distal housing portion;

first seating means in the proximal housing portion;

second seating means in the distal housing portion; and

a resilient diaphragm having a normally-closed slit therein, the diaphragm having a proximal side seated against the first seating means and a distal side seated against the second seating means, the diaphragm having a proximal surface exposed to the syringe-receiving port and a distal surface exposed to the internal valve passage;

the syringe-receiving port being axially dimensioned so that the male tip engages the proximal surface of the diaphragm so as to open the slit without penetration therethrough when the male tip is inserted into the syringe-receiving port and locked therein by the engagement between

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the locking fitting and the female fitting provided by the syringe-receiving port;

whereby the first and second seating means allow the diaphragm slit to open to allow fluid communication between the syringe-receiving port and the internal valve passage only in response to distally-directed forces applied to the proximal surface of the diaphragm, while maintaining the slit in its normally closed position in response to proximally-directed forces applied to the distal surface of the diaphragm.

2. CANCELLED

3. (AMENDED) The valve of Claim 1, wherein the first seating means comprises a first annular base and the second seating means comprises a second annular base, and wherein the first annular base is wider in the radial dimension than is the second annular base, so that the proximal side of the diaphragm is supported closer to the center of the diaphragm, and through a greater proportion of its radial dimension, than is the distal side of the diaphragm.

4. (AMENDED) The valve of Claim 1, wherein the diaphragm has a peripheral edge, and wherein the distal housing portion includes a peripheral rim concentrically surrounding and spaced from the peripheral edge of the diaphragm.

5. (AMENDED) The valve of Claim 1, wherein the first seating means comprises a first annular base and the second seating means comprises a second annular base, and wherein the first annular base is wider in the radial dimension than is the second annular base, so that the proximal side of the diaphragm is supported

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closer to the center of the diaphragm, and through a greater proportion of its radial dimension, than is the distal side of the diaphragm.

6. (AMENDED) The valve of Claim 5, wherein the diaphragm has a peripheral edge, and wherein the distal housing portion includes a peripheral rim around the second annular base and concentrically surrounding and spaced from the peripheral edge of the diaphragm.

7. (AMENDED) The valve of Claim 1, wherein the proximal and distal housing portions are attachable to each other by threaded elements.

8. The valve of Claim 5, wherein each of the first and second annular bases includes an annular bead that engages the diaphragm.

9. (AMENDED) The valve of Claim 1, wherein distal housing portion includes a main flow passage in fluid communication with the internal valve passage and extending between first and second tube connection ports, each of which is configured for the removable fluid connection with a fluid-conducting tube.

10. (AMENDED) The valve of Claim 9, wherein the internal valve passage is substantially funnel-shaped and extends from the distal surface of the diaphragm to the main flow passage through an entry orifice, the internal valve passage being wider adjacent the diaphragm than at the entry orifice.

11. (AMENDED) A syringe-actuated valve for filling a container from a syringe having a tapered, hollow, tubular male tip concentrically surrounded by an internally-threaded locking fitting, wherein the valve comprises:

a housing having a proximal portion and a

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distal portion, the proximal housing portion including a syringe-receiving port configured as an externally-threaded female fitting that is lockable with the locking fitting when the male tip is inserted into the syringe-receiving port;

an internal valve passage in the distal housing portion;

a first annular base in the proximal housing portion and a second annular base in the distal housing portion, the first annular base being wider in the radial dimension than is the second annular base; and

a resilient diaphragm having a normally-closed central slit therein, the diaphragm having a proximal side seated against the first annular base and a distal side seated against the second annular base, whereby the proximal side of the diaphragm is supported closer to the center of the diaphragm, and through a greater proportion of its radial dimension, than is the distal side of the diaphragm, the diaphragm further having a proximal surface exposed to the syringe-receiving port and a distal surface exposed to the internal valve passage; and

wherein the syringe-receiving port is axially dimensioned so that the male tip engages the proximal surface of the diaphragm so as to open the slit without penetration therethrough when the male tip is inserted into the syringe-receiving port and locked therein by the engagement between the locking fitting and the female fitting provided by the syringe-receiving port.

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12. The valve of Claim 11, wherein the diaphragm is substantially unconstrained except where it seats against the first and second annular bases.

13. (AMENDED) The valve of Claim 12, wherein the diaphragm has a peripheral edge, and wherein the distal housing portion includes a peripheral rim concentrically surrounding and spaced from the peripheral edge of the diaphragm.

14. CANCELLED

15. The valve of Claim 11, wherein each of the first and second annular bases includes an annular bead that engages the diaphragm.

16. (AMENDED) The valve of Claim 11, wherein distal housing portion includes a main flow passage in fluid communication with the internal valve passage and extending between first and second tube connection ports, each of which is configured for the removable fluid connection of a fluid-conducting tube.

17. (AMENDED) The valve of Claim 16, wherein the internal valve passage is substantially funnel-shaped and extends from the distal surface of the diaphragm to the main flow passage through an entry orifice, the internal valve passage being wider adjacent the diaphragm than at the entry orifice.

18. (AMENDED) A syringe-actuated valve for filling a container from a syringe having a tapered, hollow, tubular male tip concentrically surrounded by an internally-threaded locking fitting, wherein the valve comprises:

a housing having a proximal portion and a distal portion, the proximal housing portion including a syringe-receiving port configured as

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externally-threaded female fitting that is lockable with the locking fitting when the male tip is inserted into the syringe-receiving port;

means for attaching the proximal and distal housing portions to each other;

an internal valve passage in the distal housing portion;

a first annular base in the proximal housing portion and a second annular base in the distal housing portion, the first annular base being wider in the radial dimension than is the second annular base;

a resilient diaphragm having a normally-closed central slit therein, the diaphragm having a proximal side seated against the first annular base and a distal side seated against the second annular base, whereby the proximal side of the diaphragm is supported closer to the center of the diaphragm, and through a greater proportion of its radial dimension, than is the distal side of the diaphragm, the diaphragm further having a proximal surface exposed to the syringe-receiving port and a distal surface exposed to the internal valve passage, the diaphragm being substantially physically unconstrained except where it seats against the first and second annular bases so as to be substantially self-biased in the closed position; and

a main flow passage in the distal housing portion in fluid communication with the internal valve passage and extending between first and second tube connection ports, each of which is

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configured for the removable fluid connection of a fluid connection tube;

wherein the syringe-receiving port is axially dimensioned so that the male tip engages the proximal surface of the diaphragm so as to open the slit without penetration therethrough when the male tip is inserted into the syringe-receiving port and locked therein by the engagement between the locking fitting and the female fitting provided by the syringe-receiving port.

19. (AMENDED) The valve of Claim 18, wherein the diaphragm has a peripheral edge, and wherein the distal housing portion includes a peripheral rim concentrically surrounding and spaced from the peripheral edge of the diaphragm.

20. CANCELED

21. The valve of Claim 18, wherein each of the first and second annular bases includes an annular bead that engages the diaphragm.

22. (AMENDED) The valve of Claim 18, wherein the internal valve passage is substantially funnel-shaped and extends from the downstream surface of the diaphragm to the main flow passage through an entry orifice, the internal valve passage being wider adjacent the diaphragm than at the entry orifice.

STATEMENT UNDER ARTICLE 19

Responsive to the International Search Report dated 25 October 1994, the applicant submits claim replacement sheets 16-22 to replace pages 16-22 currently on file.

Claim 1 has been amended to clarify its terminology and to incorporate the subject matter of Claim 2, which has been cancelled. Claims 3-7, 9 and 10 have been amended to clarify their terminology. Claim 11 has been amended to clarify its terminology and to incorporate the subject matter of Claim 14, which has been cancelled. Claims 13, 16 and 17 have been amended to clarify their terminology. Claim 18 has been amended to clarify its terminology and to incorporate the subject matter of Claim 20, which has been cancelled. Claims 19 and 22 have been amended to clarify their terminology.

Fig. 1

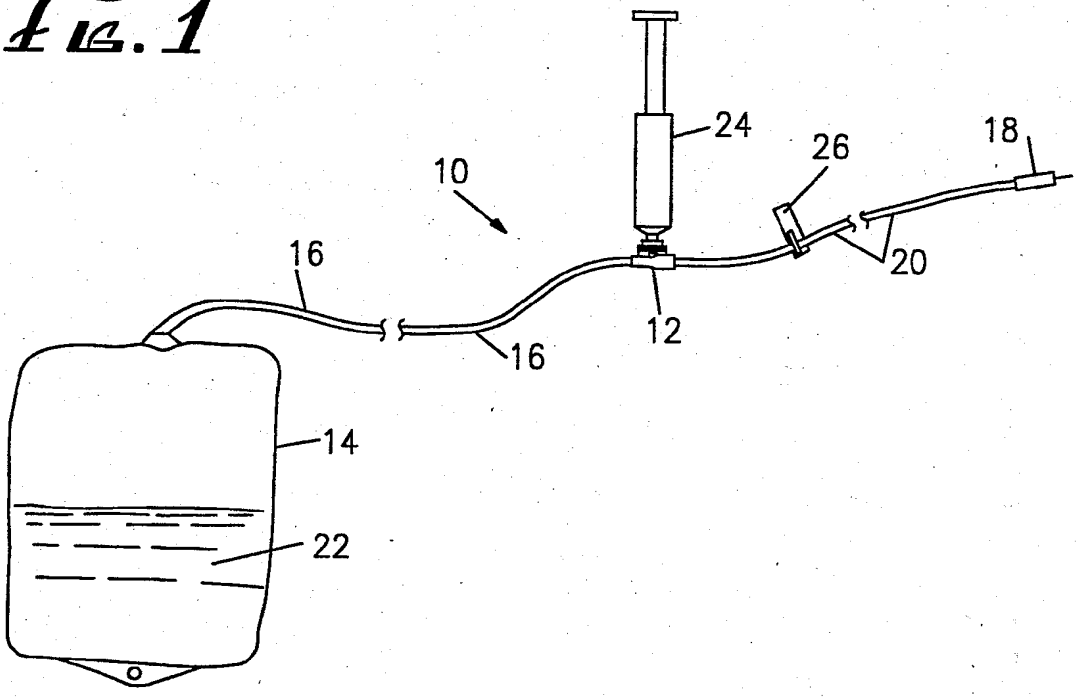
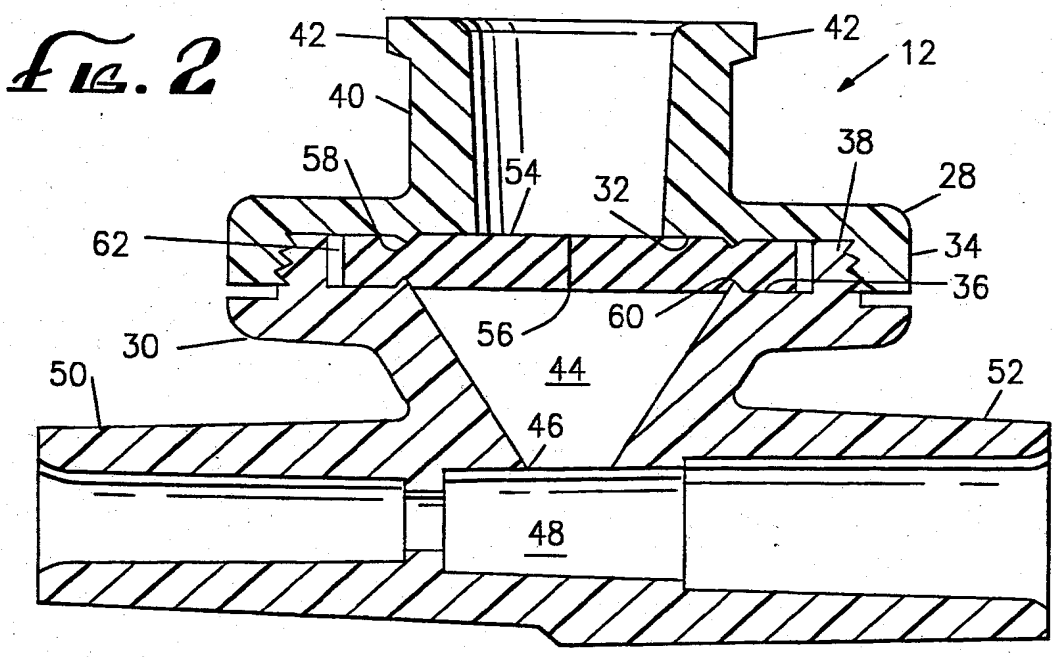


Fig. 2



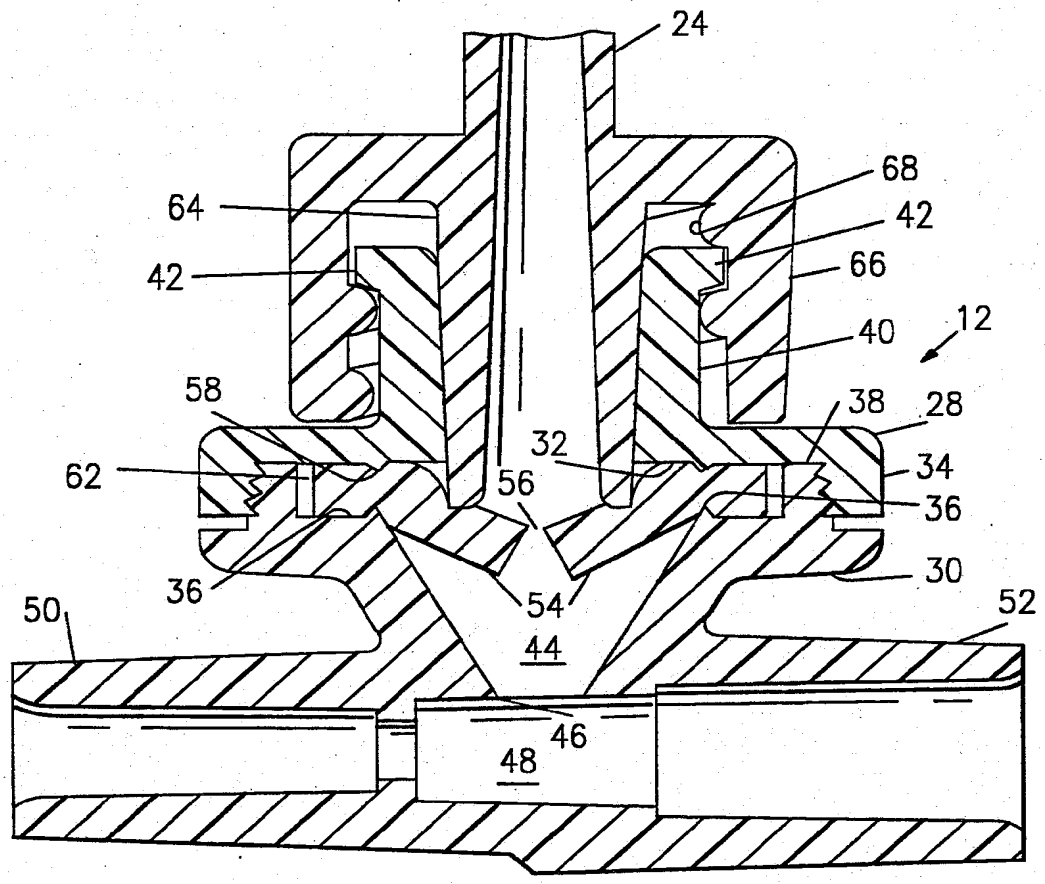


FIG. 3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US94/08245

A. CLASSIFICATION OF SUBJECT MATTER
IPC(5) :A61M 5/00, 5/178
US CL :604/167, 247
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 2k51/149.1, 145; 137/846, 849; 604/86-91, 167, 169, 200, 201, 205, 244, 246, 247, 256-258, 905

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US, A, 4,857,062, (RUSSELL), 15 August 1989. See entire document.	1-3, 5, 7, 9-12, 14-18, 20, 22
X	US, A, 4,895,346, (STEIGERWALD), 23 January 1990. See entire document.	1-7, 9, 11-14, 16, 18-20
X	US, A, 5,000,745, (GUEST ET AL.), 19 March 1991. See entire document.	1-3, 5, 8, 9, 11, 12, 14-16, 18, 20, 21
A	US, A, 4,932,633, (JOHNSON ET AL.). 12 June 1990. See entire document.	1-22

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

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